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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,522	02/25/2002	Russel E. Kaufman	1579-645	8638

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EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,522	KAUFMAN ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10,11,13-20,23,26-28 and 31-41* is/are pending in the application.

4a) Of the above claim(s) *1-7,10,11,13-20,23,26-28,31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,40 and 41* is/are rejected.

7)☒ Claim(s) *34-39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 8-9, 12, 21-22, 24-25, 29-30 have been canceled.

Claim 28 has been amended.

Claims 33-41 have been added.

2. Claims 1-7, 10-11, 13-20, 23, 26-28, 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/26/04.

3. Claims 33-41 are under examination. It is noted a request to rejoin claim 28 when claim 33 is allowable.

4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

5. The following Office Action contains some NEW GROUNDS of rejection.

Specification

6. The disclosure is still objected to because of the following informalities:

a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The response filed 2/22/05 states that the title has been amended but there is no amendment for the title in the response.

Rejections Withdrawn

7. The rejection of claims 21-22, 29-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to the claims.

8. The rejection of claim 22 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the completion of the deposit requirements and making the statements that all assurances have been met (see page 13 of response).

9. The rejection of claims 21-22 and 29-30 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendments to the claims.

10. The rejection of claims 21-22 under 35 U.S.C. ' 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendments to the claims.

The following are NEW GROUNDS of rejection

Claim Rejections - 35 USC § 112

11. Claims 33, 40-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an monoclonal antibody that binds SEQ ID NO:1 or a fragment of at least 5 amino acids of SEQ IS NO:1 and a kit comprising such, does not reasonably provide enablement for any antibody that binds to just any amino acid sequence that is encoded by just any nucleic acid that hybridizes to SEQ ID NO:2 under the recited conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to an antibody that binds to any amino acid sequence that is encoded by any DNA that hybridizes to SEQ ID NO:2 under certain conditions wherein the nucleic acid sequence does not encode SEQ ID NO:1.

The claims are not commensurate in scope with the enablement provided in the specification because the specification does not disclose a function of the K12 protein or what identifying characteristics would be needed for one to have a K12 protein.

Although the amino acid sequence of SEQ ID NO:1 is disclosed, there's no indication as to what parts of the protein are required to have a "K12" protein. The structure of the protein is required for a function to be determined and as evidenced from the following discussion protein chemistry is probably one of the most unpredictable areas of biotechnology.

For example, the replacement of a single lysine at position 118 of the acidic fibroblast growth factor by a glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (see Burgess et al, Journal of Cell Biology Vol 111 November 1990 2129-2138). In transforming growth factor alpha, replacement of aspartic acid at position 47 with asparagine, did not affect biological activity while the replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (see Lazar et al Molecular and Cellular Biology Mar 1988 Vol 8 No 3 1247-1252). Replacement of the histidine at position 10 of the B-chain of human insulin with aspartic acid converts the molecule into a superagonist with 5 times the activity of nature human insulin. Schwartz et al, Proc Natl Acad Sci USA Vol 84:6408-6411 (1987). Removal of the amino terminal histidine of glucagon substantially decreases the ability of the molecule to bind to its receptor and activate adenylate cyclase. Lin et al Biochemistry USA Vol 14:1559-1563 (1975).

These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of the protein.

The claims encompass an antibody or any compound that binds to any protein that is encoded by any nucleic acid that hybridizes to SEQ ID NO:2 and does not encode SEQ ID NO:1 and as evidenced from the above discussion it would be unpredictable what other proteins are a K12 protein.

Therefore, in view of the unpredictability in the art of protein chemistry as indicated above, and in view of the lack or guidance in the specification and in view of the broadly claimed invention, it would require undue experimentation to practice the broadly claimed invention.

The response filed 2/22/05 states that the examiners attention is directed to the fact that the language used to define the protein in the newly presented claims parallels that used in the parent case that has issued as USP 6,072,034 and accordingly the newly presented claims are clearly enabled (see page 13 of response). In response to this argument, the above rejection is made and it is well settled that whether similar claims have been allowed to others is immaterial. See In re Giolito, 530 F.2d 397, 188 USPQ 645 (CCPA 1976) and Ex parte Balzarini 21 USPQ d 1892, 1897 (BPAI 1991).

Conclusion

12. No claim is allowed. Claims 34-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832

LARRY R. HELMS, PH.D
PRIMARY EXAMINER